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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,376	07/20/2001	Chi-Huey Wong	TSRI 663.1	4021

7590 03/23/2004

The Scripps Research Institute  
10550 North Torrey Pines Road  
Mail Drop TPC 8  
La Jolla, CA 92037

EXAMINER
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RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/762,376

Applicant(s)

WONG ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 7-9 are currently pending in this application.

#### ***Claim Objections***

Claim 9 is objected to because of the following informalities: Claim 9 depends from claim 9. Correction is required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being obvious over Vann WF (FEMS Microbiology Lett., 1995, Vol. 128(2):163-166 ) or Steenbergen et al. (J.Bacteriol., 1992, Vol. 174(4):1099-1108) and Van Dijk et al. (Analytical Biochem., 1981, Vol. 117(2):346-353). This rejection is based on the public availability of a printed documents. Claims 7-9 of the instant application are drawn to a method of making polysialic acid product linked through  $\alpha$  2,8/2,9 linkage by contacting a sialic acid acceptor and a CMP-sialic acid donor with  $\alpha$  2,8/2,9-polysialyltransferase isolated from *E.coli* K92 for sequentially sialylating the sialic acid acceptor with CMP sialic acid donor followed by the step of removing the released CMP by treatment with alkaline phosphatase. It is well recognized in the art that the above strain of *E.coli* produces a unique polysialyltransferase which links sialic acid monomers through an alternate  $\alpha$  2,8/2,9 linkage. The above two references of Vann and Steenbergen et al. teach the purification and

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characterization of the polysialyltransferase from *E.coli* K92 and describes the method of making polysialic acid product by contacting a sialic acid acceptor and a CMP-sialic acid donor with  $\alpha$  2,8/2,9-polysialyltransferase isolated from *E.coli* K92 for sequentially sialylating the sialic acid acceptor with CMP sialic acid donor. However, both the above references use of steps of paper filtration and chromatography methods to separate the product formed as opposed to the step of removing the released CMP by treatment with alkaline phosphatase as claimed in the instant claims.

The reference of Van Dijk et al. teaches the use of alkaline phosphatase enzyme for removal of nucleotide phosphate and specifically from CMP nucleotide in a CMP-sialic hydrolase assay. Thus it appears that the use of phosphatase enzyme to remove the nucleotide sugars was well known in the art.

Therefore, combining the teachings of the above two references, it would have been obvious to those skilled in the art, specifically those involved in developing an alternate method to the filtration method of making a polysialic acid product as described by Vann or Steenbergen et al., and to collect the actual polysialic acid product formed, to treat the reaction mixture with alkaline phosphatase to remove the CMP side product. One of ordinary skill in the art would be motivated to do so because by treating the reaction mixture with alkaline phosphatase enzyme there is no loss of product formed and the product can be collected, further purified and used for several practical applications. One of ordinary skill in the art would have a reasonable expectation of success since Vann and Steenbergen et al. already put in place a method of making the polysialic acid product and Van Dijk et al. suggest the use of alkaline phosphatase to remove the nucleotide sugars side product formed.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

### ***Conclusion***

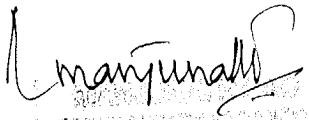
None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The examiner can normally be reached on 6.30 a.m. to 3.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Manjunath N. Rao', with a stylized flourish at the end.

Manjunath N. Rao  
March 18, 2004